

REMARKS

Applicants respectfully request further examination and reconsideration in view of the arguments set forth fully below. In the Office Action mailed December 22, 2006, claims 1-20 have been rejected. In response, the Applicants have submitted the following remarks, and have amended claims 1, 16 and 20. Accordingly, claims 1-20 are still pending. Favorable reconsideration is respectfully requested in view of the remarks below.

Rejections Under 35 U.S.C. §102

Claim 1 has been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,069,069 to Fishler et al. (hereinafter Fishler). The Applicants respectfully disagree with this rejection.

Fishler teaches an **implantable cardiac device** and method for providing monitoring of a progression or regression in heart disease over an extended time period. The Fishler reference teaches determining morphology measurements from **an electrogram** of a patient that indicate progression or regression in heart disease (Fishler, abstract). Within the Office Action, it is stated that the Fishler reference teaches deriving a total quantity of representative beats of the at least one electrocardiogram signal, and further that Fishler teaches using the data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality. In fact, the Fishler reference actually teaches an implantable device that detects an intra-cardiac signal called an electrogram signal (See Examiner citations), rather than the ECG that the present application is detecting from the torso of the patient. It is well-known in the art that morphology between an electrogram and an ECG are very different measurements, in that the electrogram is taken from an implantable device and no specific morphology features of repolarization are found in such a signal.

Furthermore, with respect to the using step of claim 1, the Examiner states that since the changes in the total quantity of values are used to indicate the progression or regression of CHF (column 2, lines 14-21), that the data is in fact being used to assess repolarization abnormality since CHF patients would have abnormal cardiac repolarization. The Applicants respectfully submit that this comment by the Examiner does not properly show the teachings of using data corresponding to at least some of the total quantity of values to assess cardiac

repolarization abnormality. The Examiner assumes that because CHF may have abnormal cardiac repolarization, that the invention taught in Fishler would in fact be used to assess such abnormality. However, as the Applicants discussed above with respect to the deriving step, because the implantable device of Fishler detects an intracardiac signal called an electrogram, such repolarization abnormality would not and could not be taught by Fishler.

In contrast to the teachings of Fishler, the method and apparatus for detecting cardiac repolarization abnormality of the present invention includes focusing on repolarization morphology features and ECG, and those features time series changes. The present application uses a group of specifically defined morphology features, none of which are taught or disclosed in the prior art listed above. The method and apparatus of the present application derives a total quantity of representative beats of an at least one electrocardiogram signal taken from a patient ECG, determines a total quantity of values representing the total quantity of representative beats using the at least one morphology shape descriptor, and uses the data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. The Applicants respectfully submit that Fishler does not teach deriving a total quantity of representative beats of the at least one electrocardiogram signal taken from a patient ECG, nor using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient.

The independent claim 1 is directed to a method of detecting cardiac repolarization abnormality using at least one electrocardiogram signal, the method comprising: deriving a total quantity of representative beats of the at least one electrocardiogram signal taken from a patient ECG; using at least one morphology shape descriptor to determine a total quantity of values representing the total quantity of representative beats, wherein the morphology shape descriptor utilizes any one of the following morphology features to determine the total quantity; a maximum morphology feature; a minimum morphology feature; an area morphology feature; an amplitude morphology feature; a slope morphology feature; and a time interval morphology feature; and using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. As discussed above, Fishler does not teach deriving a total quantity of representative beats of the at least

one electro cardiogram signal taken from a patient ECG, nor using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. For at least these reasons, the independent claim 1 is allowable over the teachings of Fishler.

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,571,122 to Schroepell et al. (hereinafter Schroepell). The Applicants respectfully disagree with this rejection.

Schroepell teaches an implantable medical device responsive to heart rate variability analysis. (Schroepell, abstract). Again, Schroepell teaches an implantable device, and as stated previously with respect to the Fishler reference the implantable device of Schroepell detects intracardiac signals called electrograms, and morphology in an electrogram signal is much different from an ECG signal. Again, the Examiner incorrectly assumes that because an abnormal heart variability is being detected by Schroepell, that this is an indication that the Schroepell reference utilizes data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. However, as stated previously, the Applicants respectfully submit that no such teaching is found in Schroepell, and in fact Schroepell is focused on change of heart rate or heart rate variability in a patient. Therefore, likened to the Fishler reference above, Schroepell does not teach deriving a total quantity of representative beats of the at least one electrocardiogram signal taken from a patient ECG, nor using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient.

Claims 1, 3, 6, 15, 16, and 20 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,531,527 to Reinhold et al. (hereinafter Reinhold). The Applicants respectfully disagree with this rejection.

Again, as was discussed above with respect to Schroepell and Fishler, the Reinhold reference teaches an ambulatory monitoring system with real time analysis and telephone transmission, that includes sampling an ECG signal that provides a plurality of ECG signal samples, and analyzing the samples in real-time and according to predetermined criteria (Reinhold, column 4, lines 30-40, as cited by Examiner). Again, the Reinhold reference teaches measuring these collected waveforms against predetermined arrhythmia criteria

(Reinhold, column 5, lines 19-21, as cited by the Examiner). In contrast to the teachings of the system and method of the present application, the Reinhold reference focuses on QRS morphology, and not specific morphology features of repolarization. Therefore, the Applicants respectfully submit that Reinhold also does not teach deriving a total quantity of representative beats of the at least one electrocardiogram signal taken from patient ECG, nor using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. For at least these reasons, claim 1 is allowable over the teachings of Reinhold.

Claims 3, 6 and 15 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Reinhold. Accordingly, claims 3, 6 and 15 are also allowable as being dependent upon an allowable base claim.

Claims 16 and 20 have also been rejected as being anticipated by Reinhold. The independent claim 16 and 21 include similar limitations to the independent claim 1, and therefore, the Applicants respectfully submit that the independent claim 16 and 20 are also allowable over Reinhold.

Rejections Under 35 U.S.C. §103

Claims 2 and 17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Reinhold in view of U.S. Patent No. 5,215,098 to Steinhaus et al. (hereinafter Steinhaus). Claims 2 and 17 are dependent upon the independent claims 1 and 16, respectively. As discussed above, the independent claims 1 and 16 are allowable over the teachings of Reinhold. Accordingly, claims 2 and 17 are also allowable as being dependent upon an allowable base claim.

Claims 4-5, 7 and 11 having been rejected under 35 U.S.C. §103(a) as being unpatentable over Reinhold in view of previously cited Cohen. Claims 4-5, 7 and 11 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Reinhold, Schroepell, and Fishler. Accordingly, claims 4-5, 7 and 11 are also allowable as being dependent upon an allowable base claim.

Claims 12-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Reinhold, in view of Cohen, and further in view of U.S. Patent No. 6,983,183 to Thiagarajan

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et al. (hereinafter Thiagarajan). Claims 12-14 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Reinhold, Stroepell, and Fishler. Accordingly, claims 12-14 are also allowable as being dependent upon an allowable base claim.

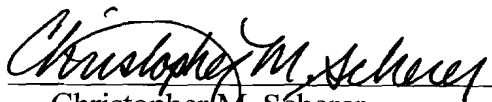
Claims 8 and 18 have been ejected under 35 U.S.C. §103(a) as being unpatentable over Reinhold, in view of U.S. Patent No. 5,713,367 to Arnold et al. (hereinafter Arnold). Claims 8 and 18 are dependent upon the independent claims 1 and 16, respectively. As discussed above, the independent claims 1 and 16 are allowable over the teachings of Reinhold. Accordingly, claims 8 and 18 are also allowable as being dependent upon an allowable base claim.

Claims 9-10 and 19 have been ejected under 35 U.S.C. §103(a) as being unpatentable over Reinhold and Arnold as applied to claims 8 and 18 above in view of U.S. Patent No. 6,847,840 to DePasquale et al. (hereinafter DePasquale). Claims 9-10 and 19 are dependent upon the independent claims 1 and 16. As discussed above, the independent claims 1 and 16 are allowable over the teachings of Reinhold. Accordingly, claims 9-10 and 19 are also allowable as being dependent upon an allowable base claim.

For these reasons, Applicants respectfully submit that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

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